

§ 73.15

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of receipt of the select agent or toxin; and

(g) The recipient immediately reports to the HHS Secretary if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package received containing select agents or toxins has been leaking or was otherwise damaged.

(h) When the select agents or toxins are consumed or destroyed after a transfer, the recipient must within five business days report such fact to the HHS Secretary in accordance with § 73.21 on a CDC Form EA-101.

NOTE TO § 73.14: This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

§ 73.15 Records.

The Responsible Official must maintain complete records relating to the activities covered by this Part. Such records include:

(a) An entity required to register under this part must maintain an up-to-date, accurate list of the individuals approved under § 73.8 for access to select agents and toxins.

(b) The entity must maintain an accurate, current inventory of each select agent and toxin held. The inventory records must include the following information for each select agent and toxin:

(1) The name, characteristics, and source data;

(2) The quantity held on the date of the first inventory (toxins only);

(3) The quantity acquired, the source, and date of acquisition;

(4) The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;

(5) The quantity used and date(s) of the use (toxins only);

(6) The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);

(7) The current quantity held (toxins only);

(8) Any select agent or toxin lost, stolen, or otherwise unaccounted for; and

(9) A written explanation of any discrepancies.

(c) The entity must maintain the following records:

(1) For access to the select agents or toxins:

(i) The name of each individual who has accessed any select agent or toxin;

(ii) The select agent or toxin used;

(iii) The date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures;

(iv) The quantity removed (toxins only);

(v) The date the select agent or toxin was returned to the long-term storage or holdings for stock cultures; and

(vi) The quantity returned (toxins only);

(2) For access to the area where select agents are used or stored:

(i) The name of each individual who has accessed the area;

(ii) The date and time the individual entered the area;

(iii) The date and time the individual left the area; and

(iv) For individuals not approved under § 73.8, the individual approved under § 73.8 who accompanied the unapproved individual into the area.

(d) The entity must implement a system to ensure that all records and databases created under paragraphs (b) and (c) of this section are accurate, and that the authenticity of records may be verified.

(e) The entity must create a record concerning inspections conducted under § 73.10(b).

(f) Safety, security, and emergency response plans.

(g) Training records.

(h) Transfer documents (CDC Form EA-101) and permits.

(i) Safety and security incident reports.

(j) The entity must maintain all records created under this part for three years.

§ 73.16 Inspections.

The HHS Secretary, without prior notification and with or without cause, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to